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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,058	02/18/2004	John Pafford	MSDI-455/PC263.33	8377
52196 7590 12/11/2008 KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709				
EXAMINER				
WILLSE, DAVID H				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/781,058

Applicant(s)

PAFFORD ET AL.

Examiner

David H. Willse

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,73-75 and 77-116 is/are pending in the application.
- 4a) Of the above claim(s) 110-116 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,73-75 and 77-109 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

The specification is objected to because of the following observations: Contrary to what is asserted at the beginning of the specification (as amended by the Preliminary Amendment of February 18, 2004), there is no evidence from USPTO PALM records or from the Applicant's own US 6,371,988 B1 that U.S. patent application serial no. 08/740,031 is a continuation-in-part of U.S. patent application serial no. 08/603,676. The status of U.S. patent application serial no. 10/114,675 needs to be updated.

The disclosure is objected to because of the following informalities: On page 5, line 9, "medullary" is misspelled. On page 8, line 14, "elevational" should be replaced by --perspective--. On page 9, lines 4 and 31, "elevational" should be replaced by --perspective--. On page 10, lines 1, 5, 7, 9, and 11, "elevational" should be replaced by --perspective--; on lines 5 and 12, "Crock" should be capitalized; on line 31, "the a" lacks proper syntax. On page 14, "bone dowel 11" (line 11), "wall 12" (line 16), and "outer engaging surface 13" (line 18) are not properly indicated in the drawings (via reference characters); on line 19, "cylindrical" is misspelled. On page 18, last line, "surgically" is misspelled. On page 19, line 3, "laparoscopic" is misspelled. On page 24, "mating threads ... 178" (line 18) and "curved portion 224" (line 21) are not properly indicated in the drawings; the lead line for reference character "226" (line 18) points to the wrong feature in Figure 37. On page 28, there is no explicit mention of element 31 (Figure 48). On page 29, line 2, "ceramic carrier 32" is not properly indicated in Figure 49. On page 32, there is an incomplete sentence on lines 14-15. On page 33, line 2, "of" should be replaced by --a--; on lines 19 and 25, "lyophilized" is misspelled. **Numerous other errors were noted, and the Applicant is advised to review the remaining pages of the original specification and drawings for similar types of problems.** Appropriate correction is required.

Claim 108 is objected to because of the following informalities: In claim 108, line 2, "flanks" should be replaced by --flank--. Appropriate correction is required.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s) (e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969)).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 3, 73-75, 77-102, and 104-109 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,371,988 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claim limitations are set forth in or would have been obvious from the claims of the patent. For example, the cylindrical bone dowel of instant claim 73 would have been inherent from the features set forth in patent claims 15 and 23, and the impregnation with a substantially pure osteogenic factor would have followed from patent claims 25 and 30. Regarding claim 74 and others, threads were quite common in the art at the time of the present invention and would have an obvious variant on the surface types listed in patent claim 16 in order to reduce or eliminate the need for impacting the bone dowel into a disc space. Regarding

claim 82 and others, a second osteogenic composition would have been obvious from patent claims 17 and 25 in order to enhance osseointegration of the spacer. The further limitations of claim 83 would have been obvious from patent claim 24 and the matrix of patent claim 18. Regarding claim 87, flattened screw threads were well known in the art and would have been obvious to the ordinary practitioner in order to better stabilize the threaded engagement with bone.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2, 3, 73, 75, 79, and 90-92 are rejected under 35 U.S.C. 102(b) as being anticipated by Wayne, EP 0 567 391 A1, which discloses a cylindrical bone dowel (column 6, lines 17-22; column 3, lines 42-46) impregnated with an effective amount of a first osteogenic composition (column 1, lines 18-21; column 2, line 51 et seq.; column 5, lines 40-51; etc.) including a first substantially pure osteogenic factor such as bone morphogenic protein (column 7, lines 35-37; column 5, lines 1-6; etc.). The cylindrical bone dowel is *capable* of engaging a concave space cut in adjacent vertebrae of a complementarily sized vertebrate, whether or not such was the intent. Regarding claim 75, the bone implant possesses mechanical properties sufficient to permit an at least low impact force for insertion into the site (column 2, lines 19-27;

column 6, lines 44-47; column 7, lines 31-34). Regarding claims 91 and 92, attention is directed to column 5, lines 50-51 and 55; column 8, line 42; and column 14, lines 33-41.

Claims 77, 78, and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wayne, EP 0 567 391 A1. Regarding claims 77 and 78, osteogenic factors such as rhBMP-2 were well known in the art at the time of the present invention and would have been obvious variants in order to provide advantages innate for such factors so as to enhance osseointegration for certain situations or indications, with the TGF- β superfamily encompassing hybrid molecules (column 5, lines 4-8). Regarding claim 85, a tool engaging hole would have been obvious in order to facilitate handling of the implant during the surgical procedure.

Claims 2, 3, 73, 75, 79, and 90-92 are rejected under 35 U.S.C. 102(b) as being anticipated by Bruce et al., EP 0 585 168 A2, which discloses a cylindrical bone dowel (page 9, lines 57-58) impregnated with a matrix or carrier and a substantially pure osteogenic factor (page 7, lines 1-11; page 9, lines 29-32; etc.). Because of its properties (page 9, lines 14-19), the cylindrical bone dowel is capable of serving as a spacer between adjacent vertebrae, whether or not such was the intent.

Claims 77 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruce et al., EP 0 585 168 A2. The further limitations of claims 77 and 78 would have been obvious to the ordinary practitioner from the discussion at page 5, lines 41-49, so as to improve bone growth at the site.

Claims 2, 3, 73-75, and 77-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grivas et al., US 5,814,084, in view of Wayne, EP 0 567 391 A1, and Bruce et al., EP 0 585 168 A2. Regarding claim 73 and others, Grivas et al. disclose all the elements except,

apparently, for the bone dowel being impregnated with a substantially pure osteogenic factor. However, such a feature was well known in the art at the time of the present invention, as seen from the above grounds of rejection based upon the Wayne document, and would have been an obvious addition to the Grivas et al. bone dowel in order to vary the release kinetics of one or more substances in a predictable and controlled manner (Wayne: column 3, lines 50-52; column 4, lines 56-58; etc.) and to facilitate subsequent bone growth into the pores (Wayne: column 6, lines 34-43; column 9, lines 45-48; etc.), with further motivation having been provided by the discussions by Grivas et al. of porous structures in the prior art (Grivas et al.: column 1, lines 19 and 53-54). Alternatively, the porous material within the implant body canal (Grivas et al.: column 11, lines 28-32) may be viewed as part of the spinal spacer as claimed, and such a material including a substantially pure osteogenic factor would have been obvious from Bruce et al. (e.g., at page 7, lines 1-11) in order to enhance the osteoinductive effects by eliminating impurities. Regarding claim 83, attention is directed to column 12, lines 1-6, of Grivas et al. Regarding claim 89, threading the tool engaging hole 15 of Grivas et al. would have been obvious in order to more stably secure the assembly. Regarding claim 101, a matrix such as a polylactic acid would have been obvious from Bruce et al. (page 7, line 24) in order to provide better control over the release rate of the osteogenic factor. Regarding claims 102 and 103, a biphasic calcium phosphate ceramic would have been obvious to the ordinary practitioner from the mixtures contemplated by Grivas et al. (column 10, lines 20-21) in order to impart the known benefits of each composition. Values within the particular ranges set forth in present claims 107-109 would have been obvious from Figure 3A of Grivas et al. and from the diversity of bone conditions found among patients.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday, Tuesday, and Thursday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

**/David H. Willse/
Primary Examiner
Art Unit 3738**